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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,578	10/08/1999	AKIKO MIYA	325/E6627	2522

7590 01/11/2006
WENDEROTH LIND & PONACK
2033 K STREET NW
SUITE 800
WASHINGTON, DC 20006

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/284,578	Applicant(s) MIYA ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Guire.

Guire teaches a solid surface modified with a linker covalently bound to the surface by photo activation of one linking group, the other linking group being bound to a biocompatible agent (abstract). Antibiotics are specified (column 6 line 160, including penicillin (claim 6). A linker comprising polyoxyethylene is disclosed (column 6 line 26). A linkage of a carboxyl group to nitrogen or oxygen is specified (column 7 lines 36-39). Polyolefins are specified as a substrate (column 4 line 33).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patnaik et al '165.

Patnaik et al '165 teach a PTFE backbone bound to a polymeric spacer with amine terminal bonds which is in turn bound to a bioactive molecule (abstract, column 4

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lines 54-59). An amide bond is specified (column 5 lines 1-5). Antibiotics are disclosed (column 6 line 29). Polymeric spacers are disclosed (column 5 lines 54-59).

The examiner takes notice under MPEP 2144.03 that both penicillin, lymecycline and benanomicin contain carboxylic acid group.

It would have been obvious to one of ordinary skill to attach penicillin, lymecycline or benanomicin to the polymer of Patnaik et al '166 in view of the fact that they contain a carboxylic acid group which can be reacted with the amine terminated spacer of Patnaik et al '165.

Claims 1-4, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al.

Goldberg et al teach a surface graft-polymerized with a monomer wherein a biofunctional agent is chemically bonded (abstract). Substrates include polyolefins (column 15 line 1). Monomers with ethylenic unsaturation containing carboxylic acid and amine moieties are specified (column 12 lines 46-67). Penicillin and tetracycline are disclosed (column 17 lines 56-57).

Regarding Guire and Patnaik '165, applicants argue graft polymerization deep inside the substrate by the claimed method, the presence of grafted chains unbound to antibiotic inside the substrate, subsequent "expansion of these (unbound) chains" upon hydration which results in more mobility of chains with antibiotics bound at the substrate surface. However, applicants claim a substrate of any thickness. Such expansion is irrelevant with a thin substrate. Further, applicants do not claim partial binding of the

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antibiotics. Regarding Goldberg et al, applicants stipulate that deep penetrating grafted chains will be created, but the number of chains will be less than with the claimed process. However, applicants claim no limitation regarding the percentage of deep penetrating chains. Lastly, it is unclear that applicants' inventive contemplated the creation of deeply penetrating grafted chains unbound to antibiotic because the disclosure does not appear to explicate such creation.

Claims 1-4, 30, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Calcaterra et al

Calcaterra et al teach graft copolymerization via electron beam irradiation of a functionalized vinyl monomer onto a base fabric, followed by reaction of the functional group with an antimicrobial with formation of a covalent bond (abstract). Polyolefins are specified (column 6 line 51). Vinyl monomers containing amines and carboxylic acids are specified (column 7 lines 6-22). Macrolide antibiotics are specified (column 10 line 4). Preirradiation is disclosed (column 8 lines 13-15). Regarding the claimed exposure to monomers in the gas phase, such a process limitation is not considered patentable during prosecution of a composition claim before the USPTO.

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500